



April 20, 2005

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Patent Application No. 10/731,824 filed 12/08/2003

Applicant: Watson Pharmaceuticals, Inc.

Title: COMPOSITIONS AND METHODS FOR MINIMIZING ADVERSE DRUG EXPERIENCES ASSOCIATED WITH OXYBUTYNIN THERAPY

Group Art Unit: 1615

Attorney Docket No. T7770.CON2

Sir/Madam:

Transmitted herewith for filing and pursuant to 37 C.F.R. §§ 1.56 and 1.97 is a Supplemental Information Disclosure Statement. Enclosed also are the following designated documents, as required under 37 C.F.R. §§ 1.97 and 1.98:

| \boxtimes | Form PTO-1449 list of <u>2</u> references submitted for consideration. |
|-------------|--|
| | Legible copies of the listed references or their relevant portions. |
| | Legible copies of the listed <u>non-patent documents and foreign documents</u> or their relevant portions are included. |
| \boxtimes | Copies of U.S. patents and/or publications are not included pursuant to the Official Gazette Notice, dated Aug. 5, 2003, waiving the requirement of 37 C.F.R. 1.98(a)(2)(i). |
| | All English translations of each non-English reference, if any, within the possession, custody, control or availability of anyone designated in 37 C.F.R. § 1.56(c) (see 37 C.F.R. § 1.98(c)). |

| require | | llowing are included within the 37 C.F.R. § 1.98: | Information Disclosure Statement if applicable and as |
|----------|---------------------------------------|--|--|
| | | Concise explanation of relevant by an English translation. | ace of each reference not in English and unaccompanied |
| | | Statement that certain listed reference. | ferences not enclosed are substantially cumulative of an |
| | | | ferences not enclosed were previously cited by or rapplication no. , filed on, which is date under 35 U.S.C. § 120. |
| if requi | | er to secure consideration of the also enclosed: | items designated above, one or more of the following, |
| | | Statement under 37 C.F.R. § 1. | .97(e)(1) or (2). |
| | | | des the amount of \$180.00 (amount in \$1.17(p)) e set forth in 37 C.F.R. \$1.17(p). |
| | ent mee credit ai | ts the requirements of 37 C.F.R. | oplies and the Examiner is not satisfied that the .§ 1.97(e), or in any other event remediable by a fee, additional fees to Deposit Account No. 20-0100 of the |
| | | | Respectfully submitted, |
| | | | M. Wayne Waster |
| | | | M. Wayne Western |
| | | | Attorney for Applicant |
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| | | | THORPE NORTH & WESTERN, LLP |
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| | JWG | 3 | Sandy, Utah 84091-1219 Telephone: (801) 566-6633 |
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N THE UNITED STATES PATENT & TRADEMARKS OFFICE

ART UNIT:

1615

EXAMINER:

APPLICANT:

WATSON PHARMACEUTICALS,

INC.

SERIAL NO.:

10/731,824

FILED:

12/8/2003

CONFRM. NO.: 4384

FOR: COMPOSITIONS AND METHODS FOR

MINIMIZING ADVERSE DRUG EXPERIENCES ASSOCIATED WITH

OXYBUTYNIN THERAPY

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

DATE OF DEPOSIT:

I hereby certify that this paper or fee (along with any paper or fee referred to as being attached or enclosed) is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir/Madam:

Please find, pursuant to 37 C.F.R. § 1.98(a)(1), the enclosed Form PTO-1449 which contains a list of all patents, publications, or other items that have come to the attention of one or more of the individuals designated in 37 C.F.R. § 1.56(c). Applicant respectfully submits that this Information Disclosure Statement is filed pursuant to:

| \boxtimes | 37 C.F.R. § 1.97 (b)(1) or (3), within three months of the filing date of the application, or |
|------------------|---|
| before a first o | ffice action on the merits, whichever occurs last; |
| | 37 C.F.R. § 1.97 (c), after a first office action on the merits, but before a Final Office |
| Action or a No | otice of Allowance, whichever occurs first, and is accompanied by either 1) a statement in |
| accordance wi | th 37 C.F.R. § 1.97(e), or 2) the fee set forth in§1.17(p); or |
| | 37 C.F.R. § 1.97 (d), after a Final Office Action or Notice of Allowance, whichever |
| occurs first, b | ut on or before payment of the issue fee, and is accompanied by both 1) a statement in |
| accordance wi | th 37 C.F.R. § 1.97(e), and 2) the fee set forth in§1.17(p). |
| While | no representation is made that any of these references may be "prior art" within the |

While no representation is made that any of these references may be "prior art" within the meaning of that term in accordance with 35 U.S.C. §§ 102 or 103, the enclosed list of references is disclosed so as to comply with the duty of disclosure set forth in 37 C.F.R. § 1.56.

Supplemental Information Disclosure Statement Application No. 10/731,824 Page 2

Moreover, while no representation is made that a specific search of office files or patent office records has been conducted or that no better art exists, the undersigned attorney of record believes that the references listed, together with any other references which may have been previously submitted or listed, are the closest to the claimed invention (taken in its entirety) of which the undersigned is presently aware, and no art which is closer to the claimed invention (taken in its entirety) has been knowingly withheld.

| LJ | A legible copy of each listed U.S. | Patent or publication (or relevant portion thereof) |
|------------------|---------------------------------------|---|
| which was no | ot previously submitted to, or cited | by, the Patent Office is enclosed pursuant to 37 |
| C.F.R. §§ 1.97 | 7 and 1.98. | |
| | A legible copy of each of the liste | d non-patent literature and foreign documents or |
| their relevant j | portions is enclosed. | |
| \boxtimes | Copies of cited U.S. patents and/o | r publications are NOT enclosed pursuant to the |
| Official Gazet | tte Notice, dated Aug. 5, 2003, waivi | ng the requirement of 37 C.F.R. § 1.98(a)(2)(i). |
| | Copies of the references listed in | n the accompanying Form PTO-1449 are NOT |
| enclosed beca | ause, under 37 C.F.R. § 1.98(d), th | ey were previously cited by or submitted to the |
| Office in appli | ication number , v | which is relied upon for an earlier filing date under |
| 35 U.S.C. § 12 | 20. | |

For all listed references that are not either in the English language, or accompanied by a translation into English, a concise explanation of relevance as required under 37 C.F.R. § 1.98(a)(3) is enclosed attached to each.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or to credit any overpayment to Deposit Account No. 20-0100.

Dated this day of April, 2005.

Respectfully submitted,

so. gramale

M. Wayne Western Attorney for Applicant Registration No. 22,788

THORPE NORTH & WESTERN, LLP Customer No. 20,551 P.O. Box 1219 Sandy, Utah 84091-1219

Telephone: (801) 566-6633

Enclosure

| O 1 P E PEO-1449 | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | ATTY. DOCKET NO. T7770.CON2 | SERIAL NO. 10/731,824 |
|------------------------------|---|--------------------------------|--------------------------|
| APR 2 5 2005 COST OF PRIOR A | ART CITED BY APPLICANT | APPLICANT Wa | tson Pharmaceuticals, |
| THE TRADEMARK OF | | FILING DATE 12/08/2003 | GROUP 1615 |

U.S. PATENT DOCUMENTS

| EXAMINER INITIALS | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|-------------------|-----|--------------------|-----------|-----------------|-------|----------|-------------------------------|
| | Al | 6,039,967 | 21-Mar-00 | Ottoboni et al. | | | |
| - | A2 | 6,562,368 | 13-May-03 | Hsu et al. | | | |
| | А3 | | | | | | |
| | A4 | | | | | | |
| | A5 | | | | | | |
| | A6 | | | | | | |
| | Α7 | | | | | | |
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| | A10 | | | | | | |
| | All | | | | | | |
| | A12 | | | | | | |

| | EXAMINER INITIALS | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION YES NO |
|---|----------------------|-----|--------------------|------|---------|-------|----------|-----------------------|
| | | A13 | | | | | | |
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| ſ | | A15 | | | | | | |
| | | A16 | | | | | | |
| | | A17 | | | | | | |

OTHER PRIOR ART (Including Author, Title, Pertinent Pages, Etc.)

| | A19 | |
|-----|--------|-----------------|
| | A20 | |
| EXA | AMINER | DATE CONSIDERED |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.